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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,722	03/27/2001	Eric Flam	FLAM 2A	1331

7590 11/03/2004  
Henry I. Schanzer, Esq.  
29 Brookfall Road  
Edison, NJ 08817

EXAMINER

BROWN, MICHAEL A

ART UNIT PAPER NUMBER

3764

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/818,722

Applicant(s)

FLAM ET AL.

Examiner

Michael Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7-28-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24,26-77 and 79-90 is/are pending in the application.
- 4a) Of the above claim(s) 41-66,77 and 83-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20,24,26-30,32-40,67-76,79-82 and 87-90 is/are rejected.
- 7) ☒ Claim(s) 21-23 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11-20, 24-26, 28, 30, 32-40, 67-72, 75-76, 77-82 and 87-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Engelman, as set forth in the previous office action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Mercer, as set forth in the previous office action.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelman, as set forth in the previous office action.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Engelman in view of Swartz, as set forth in the previous office action.

Claims 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Engelman in view of Suzuki, as set forth in the previous office action.

***Allowable Subject Matter***

Claims 21-23 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed July 28, 2004 have been fully considered but they are not persuasive. Applicant argues that Engleman nor Mercer discloses a device for distributing the weight concentrated at a bony prominence over a larger effective area and the volume in order to reduce the pressure at the interface between the bony prominence and the underling soft tissue layer. However, the claims recited in the present invention are product claims. Thus, no patentable weight was given to how the device distributes weight concentrated at a bony prominence. Any device that is attached to an appendage of the body will permit distribution of the weight at a bony prominence to occur. In the present case, the references are silent as to this function. However, one of ordinary skill in the art would recognize that any support whether rigid or flexible allows some type of distribution to occur at the bony prominence. Applicant

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argue that the prior art does not disclose a device that extends continuously between the portion of the body portion of the body part containing the body portion and the support surface for increasing the effective area and volume over which the concentrated weight is distributed. However, the devices disclosed by Engleman does extend continuously between the portion of the body and the body portion that it supports. Applicant argues that the prior art does not disclose a protective device having selected properties that have different valves. However, the properties, softness, size and thickness of the prior art are different. Applicant argues that the prior art does not disclose that the properties change over a period of time. However, the properties of any protective device will change over time. How much time is involve? Is the time limit two days or two years. Applicant argues that the prior art does not implant the device into the bony prominence. However, claim 67, it a product claim. Thus, no patentable weight was given to the whether the device is implanted into the bony prominence. Applicant argues that the prior art does not disclose a hard shell shaped to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer. However, Engelman discloses a hard shell that is fitted over a body part. That body part includes a bony prominence. Applicant argues that the prior art does not disclose a bone structure that has undergone amputation. However, as set forth above, no portion of the body can be claimed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brown whose telephone number is 703-308-2682. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yu Justine can be reached on 703-308-2675. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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M. Brown

November 1, 2004

A handwritten signature in black ink, appearing to read "Michael A. Brown", with a long horizontal flourish extending to the right.

**MICHAEL A. BROWN**  
**PRIMARY EXAMINER**